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(54) Disposable syringe

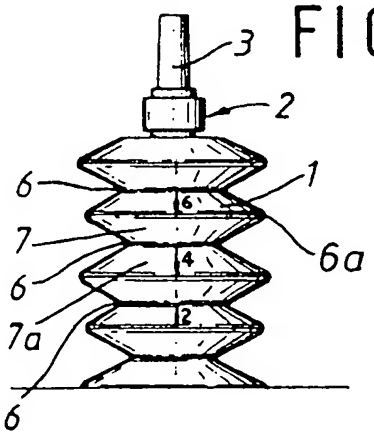
(57) A resiliently compressible variable volume casing (1), having particular application as a disposable syringe, comprises a chamber (1a) and is provided at one end region thereof with an aperture (2) for permitting transfer of a substance to and from the chamber. The casing is in the form of a bellows and has a wall defining a plurality of fold regions (6) between which are respective bellows portions (7, 7a). The casing is configured so that there is a substantial reduction in "dead space" or the air entrapped in the casing, when the bellows is compressed. This is achieved by one or more of the following:

1. forming the bellows portions so that when the bellows is compressed there is a bellows portion the periphery of which lies wholly within or wholly without the peripheries of its adjacent bellows portions;

2. providing the casing with a member mounted with respect to the casing and such that, when the bellows is compressed, the member occupies a major portion of the internal volume of the casing; and

3. forming the bellows portions each with concave and convex surfaces so that a concave surface of one bellows portion mates with the convex surface of the adjacent bellows portions.

FIG. 3.



SPECIFICATION

Disposable syringe

This invention relates to a resiliently compressible variable volume casing, for example for use with a hypodermic needle as a disposable syringe.

Routine venesection for the collection of blood samples is one of the most frequent of clinical procedures. At present, the syringes in use are of a plunger-in-barrel design and require the use of two hands by the clinician in order to withdraw blood. This means that a tourniquet is required to ensure that the vein is accessible. Further, when the blood sample has been taken, it must be transferred to a storage and/or testing vial, since the plunger in barrel design is ill suited to the storage or testing of fluid. Also, the disposable syringes in common use require precision moulding, and are relatively expensive. Of course, syringes are also used to administer medicament.

There have been proposed several syringes using variable volume bellows; however, none of these syringes have been commercially produced, and it is felt that there are three main reasons for this:

the problem of "dead space" when using a bellows type product;

the problems associated with manufacturing a completely compressible and expandable bellows; and

the problem of controlling sufficiently accurately the amount of medicament administered.

The problem of "dead space" arises as a result of the air still entrapped even in a completely compressed bellows. This can cause difficulties as air may become entrapped in a fluid being taken from or administered to a patient, with possible adverse effects. There is a British Standard which sets out the requirement of maximum dead space for conventional syringes as follows:—

Syringe size ml	*Maximum volume of dead space* ml
1	0.07
2	0.07
5	0.07
10	0.10
20	0.15
30	0.17
50	0.20

It is believed that the prior proposed bellows type syringes have not been commercially developed because they have not been able to meet these requirements.

UK 1095316 discloses a bellows type syringe having a casing forming a plurality of bellows portions, in which the end wall of the end bellows portion has a reduced structural stiffness whereby it can be collapsed completely against the other wall of the end bellows portion under an axial force. To ensure that the force is applied axially, a stud or plunger is formed with the end wall. The syringe is designed to indicate whether it has been correctly inserted prior to injection of its contents into a patient. UK 1095316 does not address the problem of "dead space", and it is apparent that this will remain a problem with the syringe described therein. Further, the manufacture of the syringe with the necessary plunger is awkward.

In the drawings:

Figures 1a and 1b show respectively, in part, a conventional bellows expanded and compressed;

Figures 2a and 2b show respectively, in part, the bellows according to one embodiment of the present invention expanded and compressed,

Figure 3 and 4 show a casing in the expanded and compressed states respectively;

Figure 5 is a plan view of the casing of Fig. 3;

Figure 6 and 7 show syringes of different capacities from the casings shown in Figs. 3 to 5;

Figure 8 shows a partial cross-section through another form of syringe having an eccentrically mounted needle receiving portion;

Figure 9 shows a partial cross-section through another form of casing having different diameter bellows portions;

Figure 10 shows a casing with concave and convex bellows portions surfaces;

Figures 11 and 12 show a syringe with an arrangement to control delivery of fluid from the syringe; and

Figure 13 shows a syringe with a housing for enabling a continuous controlled delivery of fluid from the syringe.

Figs. 1a and 1b of the accompanying drawings show a portion of a conventional bellows, in

in use as a syringe, can serve as a vial. When the casing has a substantially flat base, it is ideally suited for storage or for insertion into testing equipment to test the contents thereof.

Preferably, the casing is provided with markings to indicate the capacity of the bellows portions. These markings can be formed on a mould used to manufacture the bellows portions so as to be impressed on the casing.

The invention also provides an arrangement for delivering a desired quantity of a fluid, the arrangement including: a resiliently compressible variable volume casing defining a chamber and having at one end region thereof an aperture for delivery of fluid from the chamber, the casing being in the form of a bellows and having a plurality of fold regions between which are respective bellows portions; and a housing secured or adapted to be secured to the casing and provided with a plurality of protrusions arranged to latch the bellows portions as the bellows is compressed.

The casing can be made in accordance with any or any combination of the first to fifth aspects of the invention.

For a better understanding of the present invention, and to show how the same may be carried into effect, reference will now be made, by way of example, to Figs. 3 to 13 of the accompanying drawings.

Figs. 3, 4 and 5 show a casing in accordance with one embodiment of the present invention. The casing 1 has a hollow needle receiving portion 2 manufactured with a Luer (or any other) lock universal-sized needle-adapter portal 3. For example the adapter portal may be as described in BS 1263. The needle adapter portal 3 is provided with a hollow syringe needle 4 when the syringe is to be used (see Fig. 6), the interior of the needle communicating, via the adapter portal 3, with an interior chamber defined by the casing 1. The casing 1 has a flat circular base 5 (Fig. 5), so that the casing an be stored upright when in use as a vial.

The casing 1 is constructed so as to have fold regions: in Fig. 3 these take the form of fold lines 6, between which are defined bellows portions 7, 7a. In the embodiments of Figs. 3 to 5, the alternate bellows portions have different widths, the width being measured perpendicular to the longitudinal axis of the bellows, along a fold region 6a intermediate said bellows portion defining fold regions 6. For example, as shown in Fig. 3, bellows portion 7a is slightly wider than adjacent bellows portion 7. In Fig. 3, the difference is exaggerated for the sake of clarity. In an embodiment having a wall thickness of 0.75mm and an internal volume of 10ml. the difference may be about 0.75mm. The effect of this alternating size bellows construction on the compressiblity of the bellows is illustrated diagrammatically from a comparison of Figs. 1b and 2b, from which it can be seen clearly that the air entrapped in the compressed bellows is substantially less in Fig. 2b. In fact, using this arrangement, the wasted internal space can be reduced to about 1/10th of conventional bellows, and may be as low as 1% of the volume. Further, the compressed height of the bellows is reduced by about 50%, that is the compressed height of a conventional bellows may be about twice that of a bellows of the same volume in accordance with an embodiment of this invention.

In Figs. 2a and 2b the dimensions are as follows:

a=0.75mm
b=7mm
c=0.65mm

When the bellows is fully compressed, even with the reduced height attainable using alternating bellow portions of different diameters, there may still be some air trapped inside the casing, that is there is still some "dead space". This dead space is reduced further with the embodiment of Fig. 8 which shows a partial cross-section of a syringe without alternating bellows portions and having an eccentrically mounted needle portal 3. Fig. 8 shows the internal chamber 1a. The base 5 may carry markings indicating the patient's name and the nature of the fluid in the syringe. In this embodiment the casing has formed integrally therewith a circularly cylindrical member or piston 8. This piston 8, when the bellows is compressed, occupies most of the internal column of the compressed casing 1, thereby reducing significantly the "dead space". There will only remain as insignificant amount of air in the portal 3. The height h of the piston, as measured along the longitudinal axis of the casing, is such that it is just less than the compressed height h_c of the bellows (Fig. 7). It may be that for casings of certain capacities, and as shown in Fig. 8, it is possible to dispense with the "alternating bellows" configuration, and merely to use a "dead space" reducing piston such as piston 8. As shown in Fig. 8, the needle receiving piston 3 is placed offcentre to permit formation of the piston 8 at the needle receiving end of the casing. It would be possible to provide alternatively or additionally a piston 8' formed integrally with the base 5, as shown in Fig. 9. In Fig. 9 the needle receiving portion 2 is shown centrally of the casing, and the casing has an "alternating bellows" construction. It will be appreciated that it is also possible, referring to Fig. 8, to place the needle receiving portion 2 centrally of the piston 8, instead of in the illustrated offset position.

transparent to enable the compression of the bellows to be monitored visually, the ratchets providing a useful control to avoid over administration. With the housing 11 of Fig. 10, the spacing of the ratchets increases slightly along the housing wall since the lowermost ratchet only has to accommodate one bellows portion, whereas the next ratchet must accommodate two bellows portions, and so on. The region nearest the delivery end of the casing is free of ratchets to accommodate the fully compressed bellows.

Instead of the housing, there could be a single strip 18 with a plurality of teeth 20 to perform the same function, as shown in Fig. 12. Such a strip has an aperture 19 to fit over the needle receiving portion 2. The strip could have a plurality of teeth or a single tooth at one predetermined quantity.

As shown in Fig. 13, the syringe can be used as part of a controlled continuous drug delivery system to replace the rather cumbersome hypodermic system currently used. In this case a plate 14 is fixed to the needle receiving portion 2. An open ended housing 15 having a base 16 secured to the base 5 of the casing 1 is arranged for movement relative to the plate 14. The plate 14 serves to secure the syringe in a delivery system (not shown), which includes a drive means (shown diagrammatically as a spring 7) acting on the casing 1 in the direction of arrow A to compress the bellows. Any suitable controllable drive means could be used.

It will be appreciated that the construction of the bellows need not be such as to provide for a regular alteration between the width of bellows portions, but that it would be possible to achieve a reduction in the amount of dead space by other arrangements in which there is a bellows portion the periphery of which lies wholly within or wholly without the peripheries of both its adjacent bellows portions.

Uses of the syringe extend to all uses currently performed by standard syringes, including venesection or arterial collection of blood specimens, and intravenous or intramuscular injections. The syringe would normally be sterile-packed for immediate use with a removable end cap over the needle portal to allow the syringe to be sealed for transport of specimens.

The casing described above further has the advantages, when for use as a syringe, that it can be manufactured as a single, unbreakable, moulded unit for a fraction of the cost of conventional syringes, and may be operated with considerable control using only one hand. This one hand control reduces the likelihood of damage to a patient. A syringe of this kind may also be pre-packaged with anticoagulant or chelating agents for specific chemopathological or haematological applications, and could serve as a sample vial for the blood withdrawn. Furthermore, such simple syringes could come pre-packed with specific therapeutic fluids, thereby precluding the need for expensive vial packaging and the effort of filling the syringe. Savings in time and expense would be substantial.

A particular advantage of the casing when used as a container is that, because of the elimination of air in the compressed state, it obviates the need for using crystalline substances (for adding water, saline solution etc.) and the drugs can be preproduced in ready-to-use form. Since hospitals have refrigeration facilites, temperature sensitive drugs can be stored "on site". Suitable materials for the casing include thermoplastic polymers such as nylon polymers, polyethylene, polypropylene, surgical grades of polyvinylchloride, and ethylenevinylacetate. Further, the casing may be manufactured of a plastics material which has an additive giving UV light shielding to the plastics material for the protection of photosensitive drugs. Expiry dates for the drugs may be marked on the base of the casing in the usual way. The storage of drugs "on site" and in a convenient form for administration is particularly important where the administration of the drug is to be carried out immediately.

The syringe could also be used for administering drugs to animals in the field of agriculture or veterinary science.

The casing can be manufactured so cheaply that it can be disposed of after use. However, if required, it can be sterilised using e.g. gamma radiation, or in an autoclave, for reuse.

CLAIMS

1. A resiliently compressible variable volume casing defining a chamber, the casing being provided at one end region thereof with an aperture for permitting transfer of a substance to and/or from the chamber, the casing being in the form of a bellows and having a wall including a plurality of fold regions between which are respective bellow portions, wherein the bellows portions are so configured that, when the bellows is compressed, there is a bellows portion the periphery of which lies wholly within or wholly without the peripheries of both its adjacent bellows portions.

2. A casing as claimed in claim 1, wherein there is a set of such bellows portions, so that each bellows portion has a periphery lying wholly within or wholly without the peripheries of its neighbouring bellows portion(s).

3. A casing as claimed in claim 1 or 2, wherein there is a member mounted with respect to the casing and such that when the bellows is compressed the member occupies a major portion of the internal volume of the casing.

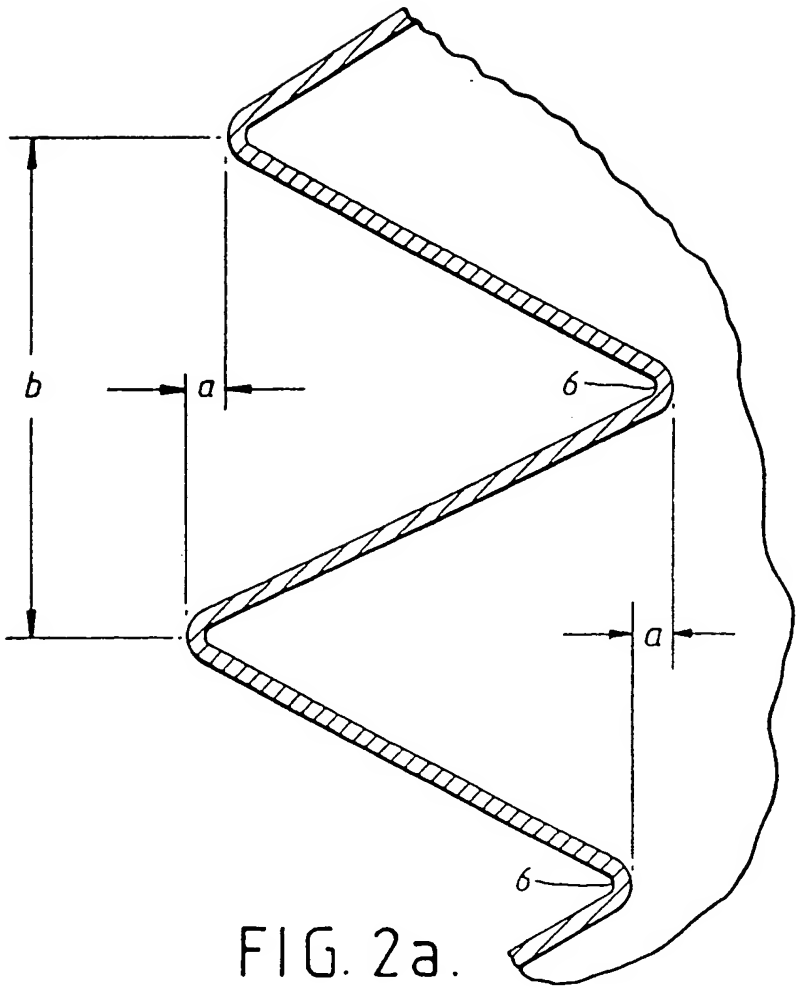


FIG. 2a.

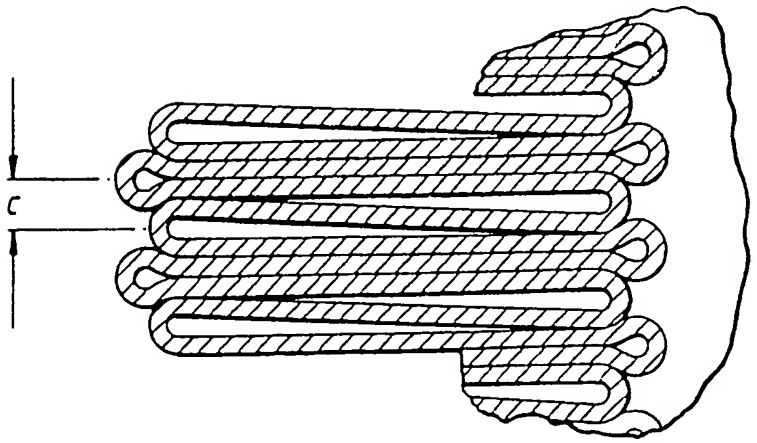


FIG. 2b.

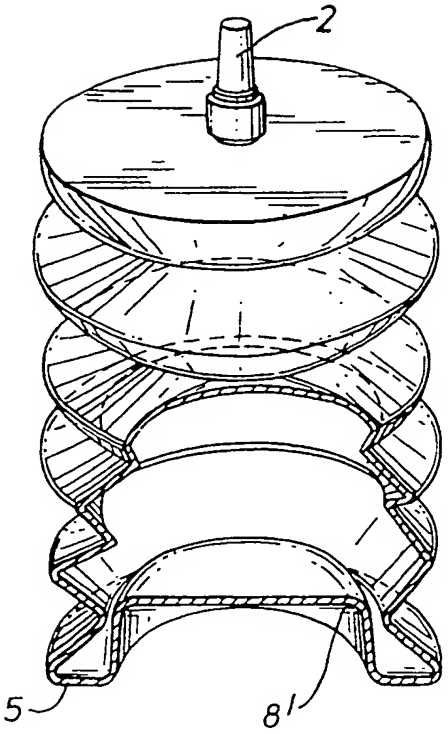


FIG. 9.

FIG.10.